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Please find below and/or attached an Office communication concerning this application or proceeding.

		1	Application No.		Applicant(s)							
			10/016,505		LAIRD ET AL.							
	Office Action Summary	Ī	Examiner		Art Unit							
			Jeanine A Goldb	erg	1634							
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply											
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less tima thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Faiture to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).												
1)⊠ F	Responsive to communication(s) f	iled on <u>30 Sep</u>	tember 2003.									
2a)⊠ T	his action is FINAL.	2b)☐ This ac	ction is non-final									
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.											
Disposition of Claims												
4) Claim(s) 27-69 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 27-69 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.												
Application Papers												
9)☐ The specification is objected to by the Examiner.												
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.												
Α	pplicant may not request that any ob	jection to the dra	awing(s) be held i	in abeyance. See	37 CFR 1.85(a).							
	Replacement drawing sheet(s) includi	-	·-	• • • • •		` '						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.												
Priority under 35 U.S.C. §§ 119 and 120												
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.												
Attachment(s	3)											
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review ation Disclosure Statement(s) (PTO-1449)		5) 🔲 1	Votice of Informal Pa	(PTO-413) Paper No(atent Application (PTC							

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DETAILED ACTION

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1. This action is in response to the papers filed September 30, 2003. Currently, claims 27-69 are pending.

- 2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
- 3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

New Matter

4. Claims 35, 37, 46, 48, 58, 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "a molecular beacon-type probe," and "a scorpion-type primer" are included. The amendment proposes that the new claim language is supported on page 8, 15 and 16 of the specification. However, the specification does not describe or discuses "a molecular beacon-type probe," and "a scorpion-type primer." Instead the specification describes dual probe technology, fluorescent primers, and fluorescence based quantitative PCR. This description does not support "a molecular beacon-type probe," and "a scorpion-type primer". The concept of "a molecular beacon-type probe," and "a scorpion-type primer" does not appear to be part of the originally filed invention. Therefore, "a molecular beacon-type

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probe," and "a scorpion-type primer" constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

The response traverses the rejection. The response asserts that hydrolysis probes, molecular beacons and intramolecular scorpion-type probes are art recognized Dual label FRET probes, and as recognized in the art at the time of filing. The response further asserts that the specification need not, and preferably does not teach what is already known to one skilled in the relevant art. This argument has been reviewed but is not convincing because the description and new matter requirement requires that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." The test is not one of what was known in the art. Inventions are typically made up of combinations of known methods to form a new method. An invention is fixed at the time of filing and adding limitations which were not present at the time of filing is not permitted. At the time of filing, the instant specification appears to discuss dual labeled FRET probes. It is acknowledged that additional probes existed in the art, however, the instant specification does not appear to contemplate or describe these probes for use in the instant method. The disclosure of a particular species would not describe a much broader genus. The response fails to provide any direct support found in the specification for molecular beacons, or scorpion type probes. The instant response has not asserted that the subject matter was incorporated by reference. However, the MPEP clearly states that "mere reference to another application, patent,

or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p)". In fact, the response provides references as exhibits to demonstrate the state of the art, rather than any support or statement in the instant specification. Thus for the reasons above and those already of record, the rejection is maintained.

5. Claims 27-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims are directed to an amplification- or amplification product-mediated conformational change of the CpG specific probe. The specification does not appear to disclose or describe the genus of conformational changes. Conformational changes include the structural relationship of the elements of the probe, the shape of the probe, including changes such as stem-loop. Each of these has not been contemplated by the instant specification. The specification fails to use the word conformation or a word including "conform." The response has not pointed to any support in the specification for the broadening of the claim. Therefore, "conformational change of the CpG specific probe" constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

New Grounds of Rejection Necessitated by Amendment Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 27-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) Claims 27-69 are indefinite over the recitation "at least one of an amplification-, or amplification product-mediated displacement or conformational change of the CpG specific probe; or an amplification-mediated-, or amplification product-mediated displacement or conformational change of the probe in relation to another probe or a primer." First, the claim appears to recite amplification product-mediated displacement or conformational change twice. The first amplification product-mediated displacement or conformational change is in relation to "the CpG specific probe" and the second amplification product-mediated displacement or conformational change is in relation the "the probe." It is unclear whether these probes are the same or whether they are different. In the event that they are the same probe, the claim appears to recite the same limitation twice in the claim. Further it is unclear what is meant by "in relation to another probe or primer." It is unclear what is being compared. Detecting displacement in relation to another probe or primer does not make sense. Further,

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displacement of a primer is unclear, as the specification does not appear to detect any such displacement or change.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 27-30, 36, 50-53, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al (US Pat. 6,017,704, January 25, 2000).

Herman et al. (herein referred to as Herman) teaches a method of detection of methylated nucleic acids using agents which modify unmethlated cytosine and

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distinguishing modified methylated and non-methylated nucleic acids. Herman teaches a method for detecting cytosine methylation and methylated CpG islands within genomic sample of DNA by contacting the sample of genomic DNA with bisulfite, amplifying the converted nucleic acid with primers which distinguish between unmethyalted and methylated nucleic acids such that at least one oligonucleotide probe is a CpG specific probe and detecting the methylated nucleic acid based on an amplification mediated change or property thereof in relation to another probe or primer. Specifically Herman teaches using MSP primers that are specifically designed to recognize CpG sites to take advantage of the differences in methylation to amplify specific products to be identified (col. 5, lines 3-5). Herman teaches that the "only technique that can provide more direct analysis than MSP for most CpG sites within a defined region is genomic sequencing" (col. 5, lines 30-35). Herman teaches a method for detecting a methylated CpG containing nucleic acid by obtaining nucleic acid and treating the nucleic acid with an agent that modifies unmethylated cytosine (col. 5, lines 58-63). The agent is preferably sodium bisulfite which modifies unmethylated cytosine, but not methylated cytosine (col. 6, lines 9-13)(limitations of Claim 29-30). Moreover, amplification is carried out using primers specific for CpG-specific oligonucleotides such that the primer distinguish between modified methylated and non-methylated nucleic acids and finally detecting the methylated nucleic acids (col. 5, lines 60-67). Herman teaches that the amplified products are preferably identified as methylated or nonmethylated by sequencing (col. 9, lines 51-55). Among the sequencing methods suggested by Herman, allele-specific oligonucleotide probe analysis is listed (col. 9.

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lines 55-65). Allele-specific oligonucleotide (ASO) probes are specific probes which allow differentiation between different sequences.

While Herman does not specifically teach a method involving ASO probes. ASO probe detection is among the list of means for sequencing the amplified products to identify methylated or non-methylated sequences. Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified and improved the method of Herman by using ASO probes for detecting the amplified products. Herman specifically teaches that the only technique that can provide a more direct analysis than MSP is genomic sequencing. Therefore, the ordinary artisan would have been motivated to have combined the MSP method of Herman with the genomic sequencing methods of Herman to obtain a modified and improved method of detecting methylated or non-methylated products. Allele specific oligonucleotide probes are used to distinguish alleles from one another. Since the genomic nucleic acid has been treated to convert un-methylated nucleic acids, the sequence differs between the methylated and unmethylated nucleic acids. The ordinary artisan would recognize that based upon the teachings of Herman that ASO probes are a means of sequencing that using this means of sequencing to provide an improved modified method would have been obvious at the time the invention was made.

Response to Arguments

The response traverses the rejection. The response asserts the rejection was already exhaustively and successfully rebutted in the issued parent of the instant application. This argument has been thoroughly reviewed, but is not found persuasive

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because the claims of the instant application are not identical to the issued claims, thus, the rejection under Herman is appropriate.

The response explains the instant invention and the method of Herman. The response asserts that Herman does not disclose or suggest CpG-specific oligonucleotide probes. This argument has been reviewed but is not convincing because following bisulfite treatment, the nucleotide sequence within a CpG island is differentially altered between methylated regions and non-methylated regions. Herman specifically teaches that the amplified products may be identified as methylated or non-methylated by sequencing such as ASO probes. ASO probes may detect the differences C and T in methylated vs unmethylated nucleic acids. Therefore, the teachings of Herman do teach a CpG-specific oligonucleotide.

The response argues that there is no teaching or suggestion to use CpG specific probes during amplification as a means to provide a real-time signal to distinguish methylated from unmethylated DNA. This argument has been thoroughly reviewed, but is not found persuasive because the claims are so unclear, as it is not clear that the claims require such a limitation (see 112/2nd rejection above).

Thus for the reasons above and those already of record, the rejection is maintained

9. Claims 31-34, 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al (US Pat. 6,017,704, January 25, 2000) as applied to Claims 27-30, 36, 50-53, 59 above, in view of Wittwer et al (US Pat. 6,140,054, October 2000).

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Herman does not specifically teach using a FRET probe to detect allele specific differences in genomic DNA which have been treated with bisulfite to analyze methylation status of the nucleic acid.

However, Wittwer et al. (herein referred to as Wittwer) teaches a method of using FRET probes to detect polymorphisms. Wittwer teaches that the methods of ASO hybridization require time consuming multiple manual steps. Therefore, Wittwer uses melting temperatures of fluorescent hybridization probes that hybridize to a PCR amplified region to identify polymorphisms (col. 1, lines 30-35). Wittwer teaches designing oligonucleotide probes identical in sequence to the complementary wild type sequence which will dissociate from the locus containing a mutation at a lower temperature than it will from the wild type locus (col. 4, lines 5-15). The probes of Wittwer contain fluorescent labeled dyes that when in close proximity the resonance energy transfer is high (col. 9, lines 7-10). The probes may comprise multiple sets of FRET oligonucleotide pairs which can be labeled with different fluorescent resonance energy transfer pairs (col. 12, lines 55-65). The method allows for a rapid procedure that can be conducted within a single reaction vessel for detecting polymorphisms in genomic DNA samples (col. 7, lines 15-25).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified and improved the method of Herman which detected allele specific differences in genomic DNA following bisulfite treatment using ASO probes with the allele specific detection method of Wittwer. Wittwer specifically teaches the method of using FRET probes to detect the presence of alleles

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or polymorphisms is less time consuming and require less manual steps. Moreover, Wittwer's method allows detection in a single reaction vessel. Therefore, the ordinary artisan would have been motivated to have detected allele specific differences in bisulfite treated DNA using FRET probes for the specific benefits taught by Wittwer.

Response to Arguments

The response traverses the rejection. The response asserts the rejection is traversed for the reasons above. For the reasons above, the rejection is maintained. Thus for the reasons above and those already of record, the rejection is maintained.

10. Claims 35, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al (US Pat. 6,017,704, January 25, 2000) as applied to Claims 27-30, 36, 50-53, 59 above, in view of Whitcombe et al (US Pat. 6,270,967, August 2001).

Herman does not specifically teach using a TaqMan probe to detect allele specific differences in genomic DNA which have been treated with bisulfite to analyze methylation status of the nucleic acid.

However, Whitcombe illustrates the use of a TaqMan probe (xyz) for allele discrimination of the ASO element (Figure 10, col. 8, lines 58-62). Whitcombe teaches that the use of TaqMan probe allows realtime or end point detection of the released fluorophore.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified an improved the method of Herman for detection of allele specific detection using a TaqMan probe as suggested by

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Whitcombe. Whitcombe specifically teaches using a TaqMan probe in the ASO detection of an allele. Therefore, the ordinary artisan would have recognized that using a TaqMan probe as opposed to an ASO hybridization would have the expected benefits of realtime detection of the released fluorophore. Therefore, the ordinary artisan would have been motivated to use a TaqMan probe in lieu of an ASO hybridization, as taught by Herman.

Response to Arguments

The response traverses the rejection. The response asserts the rejection is traversed for the reasons above. For the reasons above, the rejection is maintained. Thus for the reasons above and those already of record, the rejection is maintained.

11. Claims 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al (US Pat. 6,017,704, January 25, 2000) as applied to Claims 27-30, 36, 50-53, 59 above, in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Herman does not specifically teach packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment.

Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been <u>prima facie</u> obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Herman with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the primers, probes, and

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reagents of Herman into a kit, as taught by Ahern for the express purpose of saving time and money.

Response to Arguments

The response traverses the rejection. The response asserts that the rejection is traversed on the basis of the previous rejections under Herman. This argument has been reviewed but is not convincing because the teachings of Herman do teach using a probe in combination with primers. The response suggests that Herman uses ASO probes post-amplification. The claims to kits are directed to product claims, thus, the means in which the products are used is not essential to the kit claim. Thus for the reasons above and those already of record, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 27-32, 38-43, 50-55, 61-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent No. 6,331,393 (December 18, 2001).

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An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentable distinct from each other because Claim 27-32, 38-43, 50-55, 61-67 of the instant application is generic to all that is recited in Claim 1-26 of U.S. Patent No. 6,331,393. That is, Claim 1-26 of 6,331,393 falls entirely within the scope of Claim 27-32, 38-43, 50-55, 61-67, or in other words, Claim 27-32, 38-43, 50-55, 61-67 is anticipated by Claim 1-26 of 6,331,393. Here, claim 27 recites a method for detecting cytosine methyaltion and methylated CpG islands by contacting a genomic sample of DNA with a modifying agent, amplifying the nucleic acid with primers and detecting the methylated nucleic acid based on an amplification- medicated, or amplification product-mediated change in a property of the CpG-specific probe or in a property thereof in relation to another probe or primer. The claims of U.S. Patent No. 6,331,393 are directed specifically to detecting the methylated nucleic acid based on amplification-mediated displacement of the Cp-G specific probe. Therefore, the specific detection means claimed falls within the scope of the broad genus of detection methods allowed in Claim 27, 38, 50. Moreover, the Claims drawn to the kits, namely Claim 61 of the instant application and Claim 20 of 6,331,393 differ only in the recitation of the probe which is based on amplification-

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mediated displacement. Therefore, the claims are not patentable distinct from one another.

Response to Arguments

The response indicates that Applicants are fully prepared to timely file a Terminal Disclaimer upon notification of allowable subject matter. Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

- 13. No claims allowable.
- 14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- A) Xiong et al. (Nucleic acids Research, Vol. 25, No. 12, pages 2532-2534, 1997). Xiong teaches a quantitative technique called COBRA which introduces methylation dependant sequence differences into genomic DNA using sodium bisulfite treatment and then PCR amplified (limitations of Claim 28, 29, 30). The PCR products are digested, electrophoresed, electroblotted, oligo hybridized and phosphoimager quantified (page 2532, col. 2). As specifically seen in Figure 1, genomic DNA was treated with sodium bisulfite (limitations of Claim 27a). PCR reactions were performed using primers complementary to the converted DNA sequences with no CpG dinucleotides in the corresponding region of the original unconverted DNA (limitations of Claim 27b). The PCR products are cleaved and separated on a gel, transferred by electroblotting to a membrane. The membranes are then hybridized with a 5'-end-

labeled oligonucleotide (limitations of Claim 27c). The probe which is 5'end labeled distinguishes between unmethylated and methylated nucleic acid, as seen in Figure 1. The probe of Xiong is not a CpG-specific probe. Therefore, Xiong does not teach every limitation of the claimed invention.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist

whose telephone number is (703) 308-0196.

Jeanine Goldberg January 5, 2004

> GARY BENZION, PH.U SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600